issues. That kind of thinking underscores the need for aggressive FDA action.

Consumers must be informed whenever an allergen unavoidably might sneak into a food in which it does not belong. The challenge is to define when contamination is unavoidable and it is appropriate to say "may contain" and to distinguish that from situations of manufacturer sloppiness where "may contain" labels are not appropriate.

At one end of the spectrum, contamination clearly is avoidable when companies intentionally add rework or other material that contains an allergen into a food that is not supposed to contain that allergen.

On the other extreme, ensuring that every last residue of peanuts is cleaned out of complex equipment or a shipping container before a food that is not supposed to contain an allergen is made in that equipment or shipped in that container may be very, very difficult, especially for smaller companies.

When "may contain" statements are appropriate, they should be provided in an allergy information section of an ingredient facts label, and it should say something like: "Allergy

information: corn, wheat, may contain peanuts." "May contain" statements should be stated simply using standardized working and without explanatory language such as "manufactured on equipment that sometimes also processes peanuts." Such verbiage simply adds clutter and raises questions as Ms. Munoz-Furlong indicated in consumer's minds.

The industry's Food Allergy Issues Alliance makes a reasonable stab at deciding when "may contain" language is appropriate, but it needs improvement. First, companies that only visually inspect for allergenic ingredients, not test for them, would not use "may contain" language.

Also, the industry's guidelines are totally voluntary and some of their lawyers are advising against tests. As I mentioned, five years ago, the FDA sent a warning level to the food industry to eliminate cross-contamination. Judging from the FDA's study and the other two studies I mentioned, not enough has happened.

I think the time has long past for all this total voluntary flexible action on the part of industry.

[Applause.]

DR. JACOBSON: Therefore, the FDA should

amend its GMP regulations with a requirement for companies to take all practical measures to exclude contamination of foods with unlabeled allergens. Companies should develop HACCP plans to ensure proper cleaning of shared equipment, use of separate equipment for allergen-containing and allergen-free foods whenever possible, regular testing of products for unwanted allergens and other measures.

The best way to ensure that companies are using "may contain" only when possible contamination is unavoidable is regular unannounced FDA inspections and testing of products for major allergens.

[Applause.]

DR. JACOBSON: The FDA has already stated in its April 19 Compliance Policy Guide that undisclosed cross-contamination may cause the food to be considered adulterated. Seizures of contaminated products would protect consumers and send a clear signal to the industry that the FDA is truly concerned about food allergens and will vigorously enforce its compliance policy.

That kind of independent oversight should encourage manufacturers to maximize their

precautions. Currently FDA inspectors rarely visit factories that make cookies, pastries and other foods that may contain dangerous and unlabeled allergens. The FDA simply lacks the funds and so companies don't even have to worry about inspections.

We urge the FDA to use some of its budget increases to hire additional inspectors. In addition, we urge the FDA to seek new funding on the order of roughly $10 million a year for more inspectors, more tests, educational efforts and research to develop quick reliable testing methods.

[Applause.]

DR. JACOBSON: I hope that the food industry would recognize the value of that investment to the public's health and to its own reputation and support a funding request. In that regard, I was delighted to hear Lisa Katic say that FDA should have a strong enforcement presence, and I hope they'll join with us to lobby Congress to provide that $10 million or so in additional funding.

[Applause.]

DR. JACOBSON: Finally, to further assist consumers, as the Attorneys General recommended,

the FDA should require labels to bear a toll-free telephone number that people could call to get up-to-date information about ingredients and possible contaminants. Companies periodically modify product composition and manufacturing practices.

Many people with severe allergies like to contact companies just to make sure that labels are still correct and that accidental or incidental additives have not crept into a food that had been safe to eat.

In sum, the FDA should press industry to clean up their manufacturing practices; "may contain" statements should be used to inform consumers, but only when cross-contamination is unavoidable. And the FDA should enforce its policies by conducting more inspections and testing more products. Thank you very much

[Applause.]

DR. LEWIS: I'd like to thank all of our panel speakers for Panel II Advisory Labeling, and we will now begin a discussion either among the panel members themselves or with the FDA listening panel. Does anyone have an opening question, comment?

Dr. Wilcox?

DR. WILCOX: I'd like to address a question to Ms. Munoz-Furlong. Much of the industry discussion on good manufacturing practice and labeling focus on the eight major allergens. Does your organization agree that at this time that's the appropriate focus or do you think additional efforts also need to be placed on the less common allergens?

MS. MUNOZ-FURLONG: My belief is that if we focus on the eight major allergens, we've covered 90 percent of the problem, and once we clear that up, we should start looking in other areas, but keep it to the eight so that we can focus there.

DR. LEWIS: Another question?

DR. FALCI: This is Ken Falci of the Food and Drug Administration. Well, first of all, I think it kind of disturb me that when you take a look at the different kinds of advisory statements like "may contain" compared to "peanuts were also made in this facility," that consumers get a different kind of perspective, and that was brought out pretty well by Anne's slides.

I was just wondering does the panel feel

that that makes sense? That there is a different perception and risk as far as when people read these different kinds of terms, and is there any other survey that industry is potentially doing or anybody else that has other data that could confirm?

MS. HILDWINE: I would say that this is an area that concerns the food industry as well, and while we have not actually done a survey, I mean it's appropriate to survey consumers as to their perceptions of that labeling, and our members really aren't in a position to be able to provide that information. However, that said, the food industry is working with food companies to help them improve their good manufacturing practices to the best of the ability of those food companies.

In other words, do the best job you can. We as the association representatives are here to help you. At NFPA in particular, we have a lot of scientific expertise on staff that can be of assistance to members relative to good manufacturing practices.

Now if good manufacturing practices are sharpened, are applied in the correct way, and food products are produced in accordance with those good

manufacturing practices, then any use of a supplementary or advisory label statement that follows that will have true meaning behind it. It won't be used simply as a theoretical precaution. It will mean something, and that's what the food industry wants with those label statements.

They want them to mean something to the food allergic consumer because they want the food allergic consumer to believe them. The food industry wants food allergic consumers to see these statements and to take away the meaning that if they're allergic to the substance that's named in that statement, they should not consume that food.

Now, do we have a long way to go? We have a lot of work to do. NFPA has been working on this for a number of years. We recognize that we need to help our members more and more all the time. But we're committed to doing that and we're working on that everyday.

DR. FALCI: As a follow-up, but again the two different kinds of statements that would be out there like "may contain" or "made in a processing facility," and these would be like suggestives, precautionary statements, that the agency might want to look at maybe in the future as guides or

regulations, and the problem there is the consistency in the mind of the consumer when they actually read these kinds of different statements, and I'm just wondering that it sounds like you do agree that there is some inconsistency when you do use these kind of advisory statements.

MS. HILDWINE: The issue of the inconsistency is something that we're going to have to work on, but I would say that, first of all, since it is a label statement, it has to be true. If the food is not processed on shared equipment, then it should not use the shared equipment type statement. If it's not processed in a shared facility, it shouldn't use a shared facility type statement.

So those statements have to be true. And in order for those statements to be true, those good manufacturing practices have to be applied first.

DR. FALCI: I guess as another follow-up, when you look at "may contain," and you look at the other statement like "made in a plant that processes peanuts," though, you still get, I mean as a consumer why not not use "made in a plant that processes peanuts" even though it might be true?

Why not use "may contain"?

MS. HILDWINE: Well, "may contain" would be true.

DR. FALCI: Right. And less maybe confusing?

MS. HILDWINE: This is something that we certainly do have to continue to look at.

DR. JACOBSON: Can I ask a question?

DR. LEWIS: Dr. Jacobson, please.

DR. JACOBSON: May I ask a question? And I'll just be very blunt about this. Can I ask both of the industry representatives, and especially Lisa, you know that the FDA doesn't have resources to inspect very many manufacturing facilities. You know that the FDA has been focused on microbiological problems and looking at those factories, not factories that use food allergens.

Would your two associations support $10 million in increased funding for the FDA to conduct more testing, enforcement and research in this area?

MS. KATIC: Actually, Michael, I'll be very blunt right back. Our associations are both actively looking at more than $10 million in funding for FDA, whether it be for allergy,

microbiological inspection, or anything else that's under their purview. We think that that gives or maintains the credibility of FDA both domestically and internationally and, you know, we have seen a decline in resources, as you have, for FDA, and we think that's in the best interest of everybody including the industry that they get that funding.

[Applause.]

MS. HILDWINE: And I would just add that we're certainly not just going to wait for FDA to advance the ball relative to the research. NFPA is conducting research into testing for rapid methods that can be validated. I mean that's part of the problem, that there are some problems relative to the number of validated test methods that are out there for food allergens, and certainly NFPA is doing its part, and I know a lot of other organizations are doing their part to advance research in this area as well.

DR. LEWIS: Other questions, panelists?

DR. FALCI: Just one more--

DR. LEWIS: Dr. Falci.

DR. FALCI: --I promise. This word "unavoidable" is a troublesome word because when one has to make a decision, I guess, in industry or

in processing plants when an allergen is particularly unavoidable, and I would encourage everyone in the industry to just be more clear about the conditions that are around this term "unavoidable" in the future so that we can get a better feel for what's particularly involved.

And I guess if you want to expand on that thinking, and you start thinking about different kinds of food industries, that the word "unavoidable" might mean different things to different industries. So that you had mentioned that I believe peanuts, peanut butter plants or chocolate plants were difficult to clean, for instance, with water, and so these kinds of industries might have different kinds of unavoidable kinds of problems and maybe different kinds of good manufacturing practices that you mentioned.

And so one could lead oneself to the thinking in the future that there might be good manufacturing practices that might be applicable to different industries if one were to think about allergen control procedures. And so that's sort of a question, but it's sort of a statement, and if you have comments on that, I would be glad to take

them.

MS. HILDWINE: When we talk about unavoidable, it is always in connection with good manufacturing practices, and essentially it's, you know, the bottom line where a company goes through a process and evaluates its practices and at the end, that company says we have done the best that we can, and we still can't get rid of it. And in that case, that's unavoidable.

Now, again, different sizes of companies, different sectors of the industry, certainly are going to have to different kinds of applications of good manufacturing practices. And we are committed to working with all of our members regardless of size to help them improve their GMPs. So that if they go through the process and then have to use or have to consider supplementary labeling, that that supplementary labeling will have true meaning to the food allergic consumer.

DR. JACOBSON: I think that you're going to have to end up deciding what's avoidable and what's unavoidable. I mean drawing a distinction, it's like drawing a line in the Potomac River. It's not going to be very clear. But it's going to be, I'd much rather trust FDA inspectors evaluating

when a "may contain"--when an ingredient is avoidable or unavoidable than a manufacturer's discretion.

DR. LEWIS: Kathy.

MS. GOMBAS: Yes, this is Kathy Gombas with FDA, and this is actually an Alliance question so either GMA or NFPA. We're talking about GMPs, I'm wondering if the Alliance has started looking at and identifying specific GMPs for the various products and processes that are out there that would minimize allergen cross-contact?

MS. HILDWINE: Okay. I'm doing this one, too. First of all, just to clarify, Anne Munoz-Furlong is also a member of the Food Allergy Issues Alliance, but that said, a number of the associations that are members of the Food Allergy Issues Alliance have already developed guidance relative to GMPs for their members, and these associations within the Alliance, many of them are specialized associations that represent particular sectors of the industry. I don't know if you guys want me to name you, but there's bakers, there's candy and convection, there's dairy product associations, there are a number of associations whose manufacturing practices have some very

specific concerns related to food allergies and they have already done a lot of this work.

They've shared this work with the Alliance and so we're all learning from that. NFPA is working on this now. This issue is what resulted in our code of practice. And now we are developing some additional guidance to help our members regardless of what sector they are in to improve their GMPs. So there's a lot of work to go around for everybody and every association that's in the Food Allergy Issues Alliance has been dedicating a lot of energy over the past several years to this particular issue on behalf of their members and we're no exception.

MS. KATIC: Just adding on to that, ditto everything that Regina said, but we have looked at that as an item for future discussion and further review specifically because we've been focusing so much on our labeling program. That's obviously taken up the bulk of our time, but certainly have not discounted that there might be a need to look further into what you asked down the road once we've got the labeling part well defined.

DR. LEWIS: Other comments from panelists? Well, while you're cogitating for a few moments

because your time is not up, we'll move to some of the questions we have. We have quite a few. I do want to mention that we've received several questions for Theresa Dziuk, who reported on the Food Allergen FDA/State Partnership. Relative to any of those types of questions, you may access any information that the agency has on the website. It is at cfsan.fda.gov. And the search for the word "food allergens," which again is on our web page.

In addition, we mentioned the state attorneys general petition. That also is available at Dockets and the contact information is in your Federal Register. So questions on that can be answered elsewhere.

We do have a series of questions. Again, if the panel has something to add, please do feel free to jump in. But one question is how would the panel, and this is obviously directed to all of you, how would the panel suggest dealing with imports? States have reported more allergy labeling problems with imported foods than with domestically produced foods, according to this question.

MS. MUNOZ-FURLONG: I'm going to give you the consumers' perspective. You raise an

interesting point because we have consistently found that when one of our members has a problem, and it's caused by an imported food, we have no recourse. We can't call the company like we could with a domestic product, and they're on it and instantly we are correcting the information, getting the news out to our membership.

So as a result of that, we advise our members not to eat imported products because we can't guarantee that the label is correct, and that we will be able to trace back any information they might need if they have a reaction.

MS. HILDWINE: Imports are a particularly challenging issue. I mean if you look at recall track record, there is a lot of imports on a regular basis and food allergen related recalls.

All the audience may not know this, but this is a true fact. Imported foods are subject to the same requirements as foods that are produced and sold domestically. So imports should be observing good manufacturing practices and labeling accuracy as well as domestic production.

Now, that said, the Food Allergy Issues Alliance has, in fact, worked some outreach relative to other nations. As we were developing

our food allergen labeling guidelines, we had representative from the Canadian food industry who worked with us on that, and we are of the understanding that food allergen labeling guidelines and, of course, the good manufacturing practices sector that's included in there on supplementary labeling, that that's under review for adoption by the food industry in Canada.

In addition, we as a food industry have liaisons with food industry around the world. We've made sure that the Food Allergen Labeling Guidelines are in the hands of a number of representatives for sharing with their producers in other countries, and certainly we are doing the best that we can as an Alliance to make sure that the concepts in the Food Allergen Labeling Guidelines, that these are known around the world.

A number of our members are multinational corporations that are disseminating food allergen GMP and labeling information to their companies in other nations. So we are really I would say engaged in a vigorous effort to make sure that this information gets known around the world.

The United States is probably in the lead in terms of its contemplation of this issue.

Certainly, the advancement of science in the U.S. is far ahead, I think, of what's going on in other nations, and we are trying to bring the rest of the world along on this issue.

DR. LEWIS: Any other comments on imports? We have a question concerning legal liability. The question is really in two parts. What is the legal liability risk to a manufacturer if a consumer is injured by an undeclared allergen? And then also the legal liability risk if undeclared allergens are found in a food, thereby putting a significant number of individuals at risk?

So again I think the question is asking for some clarification as to how legal liability is perceived here.

MS. HILDWINE: I'll do this one. I'm not a lawyer. I don't think we have any attorneys on this panel. And so I'm not going to be able to answer this question directly. However, the last thing that any food company wants to do is to cause harm to anybody. And so the issue of risk is certainly something that all food companies have to take into consideration as they engage in their normal operations.

DR. LEWIS: This question talks about

preventing manufacturers from using "may contain." That is how can you prevent manufacturers from using "may contain" as a substitute for GMPs? What controls are or should be in place? And this is important since it artificially restricts consumption of those products, artificially restricts consumptions of products for those who already have limited choices.

Does anyone care to address that question? Regina, I have a question directly for you next so I would suggest you hold off for a second.

MS. KATIC: Could you repeat the beginning of it? It's about how to prevent?

DR. LEWIS: How can you prevent manufacturers from using "may contain" as a substitute for GMPs?

MS. KATIC: Well, I think this has already come up in some form briefly, but certainly I think Dr. Jacobson and I are in agreement that FDA has the authority to enforce and we certainly support full enforcement of FDA inspecting and maintaining these practices within plants.

As I stated in my comments, this is being done within all of our member companies which make up probably 90 percent of, as Anne stated, the

allergens that we're talking about. So, you know, you could mandate the fact that we can't use "may contain," but then you're faced with as, I tried to lay out, some very clear examples of when "may contain" is absolutely necessary to preserve for manufacturers.

This is also why the industry responded so quickly and got on board with our labeling program through the Allergy Issues Alliance because we understand that this is a critical problem. It's one that we want to fix or work toward providing a solution so that "may contain" can be preserved and therefore believed and used by the food allergic consumer.

DR. LEWIS: Go ahead, Dr. Jacobson.

DR. JACOBSON: When you say the industry reacted so speedily, were you referring to the response to the 1996 letter?

MS. KATIC: Well, I think we've, you know, as has been indicated by both Regina and I, this is an issue that the industry has been dealing with much longer than the '96 letter.

I don't think you can point out from that letter, unless you have some very specific examples, I don't think that you can say that

industry has not responded or developed good manufacturing practices.

Certainly, they continue to look at their practices to see where they can do better. You know I'm sure that most of our member companies have done that since the letter in '96. I guess that's pretty much it.

DR. LEWIS: And actually building on a point you raised earlier, Lisa, we have two questions that are more or less related. How many companies in the U.S. are not members of GMA or NFPA and how does GMA and NFPA plan to ensure compliance of its new labeling and manufacturing guidelines both among members and what might you do about non-members?

And then related to that, is there currently a penalty for companies using "may contain" warnings when not meeting the four criteria? If so, what is it? If not, what motivation do they have?

MS. KATIC: Well, I guess I wish we knew how many companies are out there that are not members of either association. I don't know that anybody has those numbers or figures. As I stated earlier, we do see that as an area in need of some

attention, and also have stated that we've already looked at through the Alliance how we would reach out not only to members, smaller members within our associations, but also those small manufacturers that are not members of associations.

And I think through the Alliance as we've said we have a broad group of about 20 associations. I think every association knows, you know, who some of those members are that aren't a part of their association. So just by nature of the type of business that they do, we would already be able to name I would say quite a few.

You know the real challenge is getting to the real mom and pop type operations and I think we probably need to have a discussion about that collectively on how we reach those types of operations. I've now forgotten the rest of the question so I--

DR. LEWIS: It regards penalties for using "may contain" when not meeting the four criteria.

MS. KATIC: Penalties within our, I guess--

DR. LEWIS: Presumably, yes.

MS. KATIC: --our program. Well, we don't have anything necessarily laid out. I can tell you

that in working with the industry for some time, we mentioned earlier that we have a baseline survey that we're starting and will continue to survey membership amongst all of the trade associations in the Alliance, and it's generally that when industry seems a program picking up, and really gaining some significance, it's rare that--I mean certainly there are companies that don't adopt it, but it just adds to, I think, the importance of the program and makes it almost imperative that companies do adopt the program and basically get on board.

So I think just by nature of them hearing that this is something that's really gaining significance amongst the entire industry, by nature of competition, if you will, it encourages those that are outside the program to participate. So there is not an outright penalty, but there is an incentive there.

MS. HILDWINE: And just to elaborate a little further on some of the things that Lisa said, the Food Allergen Labeling Guidelines have been made public. They certainly are in a public area of NFPA's website. I know they're in the public area of a lot of food companies' web sites.

I personally sent, made sure that companies that are not members of NFPA received the guidelines when they asked for them. Now that was followed up with a call from our membership office.

Nevertheless, we have reached out beyond our memberships to other food companies and, of course, every member of the Alliance has been presenting on their website Food Allergen Labeling Guidelines.

I think, Anne, you have them on your website, too. So these are not a secret. They are readily available, and if anybody is not a member of NFPA and would like the Food Allergen Labeling Guidelines, just give me a call, and we'll make sure that you get a copy of the guidelines so that you can start to get on board with this very important initiative.

DR. LEWIS: And while you still have the microphone, a question specifically for you. Does the food industry currently have standard definitions for the various precautionary statements? If so, can they be located? If not, what can a consumer use as a guide for interpreting?

MS. HILDWINE: Right now through the work

of the Food Allergy Issues Alliance, we did discuss three types of statements, and they're the statements that FDA has asked questions about in the Federal Register notice.

Now, as to standard definitions, unfortunately there are none. However, since any information that appears on a food label has to be true, those statements would have to represent what they say. In other words, if it's processed on shared equipment, it would have to mean that it's processed on shared equipment. Now, as to a measure of risk, which I understand is probably at the underpinning of this question, again, I don't think that this is an area where the food industry wants to encourage food allergic consumers to try and understand relative risk.

The whole purpose of those supplementary or advisory statements "may contain" is to send a message to the food allergic consumer do not eat this product if you are allergic to this food. In other words, to believe what it says, because we believe that food companies are using these statements responsibly. And that proportion is increasing because of the Food Allergen Labeling Guidelines, and certainly we hope that over time

these statements will become increasingly more believed, and secondly, increasingly rare.

DR. LEWIS: For Anne Munoz-Furlong, we have a question. Isn't the lesson here that it's important to look at all food labels all the time? Why is there a different standard if the label adds "may contain" versus peanut as an ingredient?

MS. MUNOZ-FURLONG: Absolutely, you need to read the label all of the time. We are talking about the additional information that is being put on these labels and how the consumer is interpreting them, and what the impact of the proliferation of these statements has been on the consumer's purchasing decisions and purchasing habits.

But the first place that a food allergic individual has to go is that ingredient statement. Unfortunately, if you take the example that I gave with the raisins on the airplane, there's a bag of raisins. There are raisins in the bag. You have looked at the ingredient declaration. It says raisins and then underneath it, it says may contain peanuts. What are you going to do if you're allergic to peanuts? That's the answer we are looking for from industry and the FDA.

How are you to behave when you see that? Are you never to eat raisins again because they all may contain peanuts? That's unclear to us at this point.

DR. LEWIS: This next question is to Dr. Jacobson as well as all members of the panel. It says Ms. Katic stated that cleaning will not succeed in removing all allergens. Given this, would you support precautionary labeling for all food manufactured on safe equipment and if not, why not?

DR. JACOBSON: What was that? Would I support?

DR. LEWIS: Support labeling for all food manufactured on shared equipment.

DR. JACOBSON: Well, I would assume that some--that it's possible to clean well some shared equipment. And it's something where the FDA would have to go in and make some evaluations. Maybe chocolate, you can't clean it adequately and maybe that's where dedicated lines should be used if at all possible. But I would think it's a judgment call, not a blanket rule saying always use "may contain."

DR. LEWIS: Others have comments on that?

MS. MUNOZ-FURLONG: I would agree with that. What we want to do is move away from "may contain," not add it to every single ingredient, because as we see now, there is so much confusion and limited food choices perhaps unnecessarily. We want to move away from that.

DR. LEWIS: This question goes to the four pronged test. It's know that microscopic amounts of allergens can harm sensitive people. Please explain why the first prong of your four-prong test for precautionary labeling is adequate. It allows for visual inspections alone.

MS. KATIC: I think, first off, what we mean by visual is you know you're using, you know, an ingredient that has an allergen in it. So I think to me that's kind of obvious. Maybe that's not to everybody else. It also states there that analytical testing can be used for purposes or situations where it might not be as visually obvious.

MS. HILDWINE: The first prong of the four-prong test reads exactly: The presence of a major food allergen is documented through visual examination or analytical testing of the processing line equipment, ingredient or product or other

means, so visual examination is only one thing that's mentioned there. Lisa mentioned also that analytical testing is there.

Certainly documentation, paper trail, may also demonstrate that the major food allergen is in that environment. So we're not relying on visual examination alone.

DR. LEWIS: I'm going to stop with the questions there, but turn back to both the FDA listening panel as well as our presenters and ask if there are any further comments or questions from you folks. Kathy.

MS. GOMBAS: Kathy Gombas with FDA. Regina, in the first panel, you had indicated that perhaps it was the Alliance that was going to conduct a survey to get more information on who had gone to voluntary labeling for plain English. Are you going to do the same thing for the advisory labeling, and if so, are you going to ask them why they're using advisory labeling?

MS. HILDWINE: That's in the survey as well. The survey covers all of the areas that were addressed in the Food Allergen Guidelines. So we do ask them if they have control procedures and various other questions related to supplementary or

advisory labeling. And the data that we're collecting will essentially be baselines.

DR. JACOBSON: Can I ask a question of FDA for informational purposes only?

DR. LEWIS: As I recall, we're in a listening mode, Dr. Jacobson, but feel free to put it on the table.

DR. JACOBSON: For informational purposes, I wonder if Dr. Falci could give us some sense of how frequent inspections are, say, of a cracker or cookie company of $25 million a year in sales? How many times a year, a decade, ever an FDA inspector will look at these allergen issues?

DR. LEWIS: We actually get frequently questions about how often that happens, and to be honest, Dr. Jacobson, I don't have that information for you right now, but we'll try to get back to you with it.

I do want to turn to some administrative issues concerning the public speakers who are scheduled to present this afternoon. We will be using the first three rows of what for you is the left-hand section, for me the right-hand section.

So for those of you that have registered to speak as public commenters, please either gather

a little earlier from lunch or at least plan to sit here as soon as you return. Our lunch break is scheduled to go until one o'clock, and I can promise you we will begin promptly at one o'clock, so please do feel free to take a lunch break, but remember we will be starting at one o'clock, with our third panel. Thank you.

[Whereupon, at 12:10 p.m., the meeting was recessed, to reconvene at 1:05 p.m., this same day.]

A F T E R N O O N S E S S I O N

[1:05 p.m.]

DR. LEWIS: Panel III focuses on the labeling of ingredients exempted from declaration. There's two categories here: common or usual names and incidental additives.

Before I begin, I would like to introduce a new member of our panel, Mr. John Hallagan. As we said, he was General Counsel for FEMA, ASTA and IACM, and he's replaced Ms. Katic on our panel.

Our procedure at this point will be to allow our four panel members, Dr. Jacobson, Ms. Munoz-Furlong, Ms. Hildwine, and Mr. Hallagan, to each address the topic of labeling ingredients exempted from declaration, and then we will move to discussion.

Dr. Jacobson.

DR. JACOBSON: Currently, food labels are not formally required to disclose allergens such as peanuts, wheat, casein or carmine when they serve as flavorings, spices or non-certified colorings. However, undeclared colorings and flavorings have caused occasional allergic reactions. Examples include carmine, saffron and annatto colorings, partially hydrolyzed casein and peanut flour. Also

such spices as allspice, cardamom and coriander have caused occasional allergic reaction.

While disclosure is not required, in 1996, the FDA sent a warning label to companies urging that they voluntarily declare on labels any allergenic components of such ingredients. I agree with University of Nebraska food allergy experts, Steve Taylor and Sue Hefle, who wrote in a paper if an ingredient is known to be allergenic even on a rare basis, such as carmine or papain, then it should be declared on the ingredient statement.

Unfortunately, the FDA has not determined that it has legal authority to require labeling of those additives when health is at issue. It should assert that authority by commencing a rulemaking as requested by the nine attorneys general more than a year ago. CSPI also will be submitting a formal request for that action in the near future.

The FDA could take several legal approaches. It could assert that the general misbranding section of the act trumps the flavoring/spices/colors exemption because the ingredients can cause severe allergic reactions.

Alternatively, for allergenic flavorings, spices or colors that are considered generally

recognized as safe, the FDA could determine that those substances are not safe. They can only determine it safe if labels disclose the presence of those substances.

Third, in the cases of approved color additives and food additives, the Act allows the FDA to set conditions of use, such as label disclosure. Thus, FDA should amend its regulations to specify that any allergenic coloring or flavoring additive must be declared on the label, as it has for Yellow 5, or monosodium glutamate, and certain other foods.

We urge the FDA to require disclosure not just of the major eight allergens but others as well. To someone with an allergy to corn or carmine, it's no satisfaction that wheat and shrimp are disclosed.

The cost and inconvenience to companies of providing disclosure is a small price to pay for protecting the health of sensitive consumers.

Therefore, as a general policy, the FDA should require, not just strongly encourage, labels to disclose allergenic ingredients in the flavorings, colorings, and spices. Labels should simply declare something like colors includes

carmine or natural flavoring includes peanuts, and then in the allergy information section of the label, the presence of the major allergens should be highlighted.

Moving now to incidental additives. Those are substances that are present at insignificant levels in food and that don't serve any technical or functional effect. Incidental additives have never been disclosed on labels, but in 1996, the FDA told the food industry that such additives are not insignificant if they might cause serious allergic reactions and that they had to be labeled.

And that was incorporated into the FDA's compliance policy guide earlier this year. While incidental additives are present at low levels, and to my knowledge have not caused known allergic reactions, it's worth noting that the EPA recently expressed concern about the allergenicity of StarLink corn. It banned--it banned the presence in food of any amount, even under 20 parts per billion, of StarLink even without proof that it ever caused an allergic reaction.

Today, no one is talking about banning wheat, corn or other allergin, but only requiring label disclosure. The FDA's policy concerning

allergenic incidental additives should be incorporated into a regulation that states explicitly that any incidental additive that may cause a serious allergic reaction should be presumed to pose a risk and be declared in the ingredient list.

If an incidental additive is one of the main food allergens, or sulfites, it also should be declared in the allergy information section of the ingredient facts label. Regulations could allow waivers if companies can demonstrate that the amount of allergen present is truly too small to cause any reactions. Thank you very much.

[Applause.]

MS. MUNOZ-FURLONG: Before I begin, I want to also again clarify that when I talk about flavors during my presentation, I really do intend this to apply to flavors, colors, spices and incidental additives.

Next slide, please. My objectives here are going to be to provide the consumer's perspective on these incidental additives and provide information about the industry's response to the concerns of the food allergic consumer, and that's going to be based on information from our

members and the industry itself.

Next slide. First of all, from the consumer's perspective, we know that strict avoidance is the only way to avoid an allergic reaction. We know that major allergens can be included in flavors, spices and colors and incidental additives. We also know that they are currently not required to be listed on the label, and that children have had allergic reactions to proteins even in the low levels that you're going to find them in these categories.

A good example of this came to us several years ago when a cereal was put on the market. Within weeks after launching this cereal, we started to receive calls all over the country about children having allergic reactions. We contacted the manufacturer. They found that, in fact, the flavorings contained milk ingredients.

Now, to their credit, they changed the label to reflect that information, and we have not had any reports of incidences to that cereal since then.

Next slide. When a consumer sees natural flavors on the market, they have several options. The first one is avoid that product completely. If

any of you have ever looked at the ingredient statement, you will know that if you avoid the products that say flavors, colors, or spices, you're going to have no food choices at all.

The second is to take a chance. Again, we're talking about children, so this is not acceptable as an option.

The third is to decide to call the manufacturer and ask very specifically does the flavor contain whatever the protein you're trying to avoid. If you make that determination to be your decision, then you need to hope, first of all, that there's a phone number listed on that package to help you make that phone call.

Many of these calls are being made at the grocery store on cell phones as people look at a package, want to make a purchasing decision on the spot, or at dinner time when they are taking a product off the shelf in their pantry and notice an ingredient that they don't understand. So the need for information in a timely fashion is critical in these situations.

Next slide, please. Now, currently some companies will divulge the information willingly and quickly over the telephone. We applaud their

efforts. However, other companies will consider this information proprietary and will not release it.

We have had some companies tell our members that if they have a reaction, their doctor can call the company, and then they will divulge all this information. This doesn't seem to be the way we should be doing this.

Some of the companies will provide the information, but in writing, and it takes several weeks to get this information that will not satisfy the need of our members to get information quickly. There are a few companies that will provide this information in a timely fashion. They will put it on the label.

For example, natural butter flavor or natural flavors contains milk. This saves time. It's simple English and it's very easy to understand.

Next slide. Now, again, going back to the survey that I've mentioned today several times. Second on the list of top three concerns in the write-in portion of our survey was natural or artificial flavors or colorings. The concern from our members is that this has hidden ingredients,

and if you recall from my first presentation, reactions occur because someone is eating something they think is safe. If they don't know the allergen is in there, they can't avoid it.

Next slide, please. The conclusions from our survey showed that food allergic individuals are reading the ingredient label diligently. They are making purchasing decisions that affect their health based on that information.

We also know that they believe that the information on the package is not complete. Four out of five of them report calling manufacturers for additional information. I want to make the point that our members are one of the best educated, highly motivated people in the food allergy community and this country. If they are struggling with these labels, I can only imagine what the general public is going through.

Now, the final slide, in summary, flavors, spices, colors and incidental additives can contain hidden ingredients. Even the low levels of allergens that would be present in this could cause a reaction affecting children most often. Therefore, we recommend that allergens should always be declared on the label when they're

present in a product.

Thank you.

[Applause.]

MS. HILDWINE: Thank you. At the outset of the discussion on labeling allergenic components of flavors, colors, spices and incidental additives, it's important to note that major food allergens are proteins. There are numerous components in flavors, colors and incidental additives that are not proteins.

Often these components include alcohols or oils that may be derived from the major food allergens, but are so highly refined that they do not contain protein. Bleached, deodorized and refined soybean oil that may be used as a carrier for flavor or color or a component in a food additive in some food applications is a good example of the type of product that should be considered outside the scope of today's discussion.

Furthermore, there is no spice included among the list of the eight major food allergens that is the focus of FDA's discussion today, so it is clear that in this session, we really are speaking of spices only in concept.

This observation leads one to the

conclusion that FDA should continue to address the labeling of allergenic components in flavors, colors and spices on a case-by-case basis. Creating a generally applicable policy most likely would encompass substances that are not at issue for the labeling of food allergens.

We know from our discussions with NFPA members that they receive information from their suppliers of flavors, colors, spices and additives with respect to the allergenic components present. NFPA believes that suppliers should always volunteer this information to their food processor customers with the understanding that food companies are not interested in knowing the formulation of the flavor, color, spice or additive, just in knowing which allergenic proteins are present.

NFPA also is of the view that food processors should carry forward to their own labels information on the presence or possible presence of those major food allergens and flavors, colors, spices and incidental additives.

NFPA believes it is appropriate to present plain language information on the allergenic components of flavors, colors, spices and

incidental additives in association with the ingredient declaration of the finished food.

This information should be in the ingredient list where the flavor is declared or at the end of the ingredient list as appropriate to the food and the flavor or other component.

The presentation options--"contains," use of a reference mark or use of parentheses--as discussed in this morning's session on plain language, all are valid presentations as would be any plain language representation of the name of the allergin in the common or usual name of the flavor.

NFPA would not support rulemaking to make mandatory the ingredient declaration of the plain language terms for major food allergin components of flavors, colors or spices. Many of our members already declare information on these allergenic components on a voluntary basis.

NFPA believes it is the responsibility of food processors to obtain this information from their suppliers and carry it forward to the finished product labeling. Many of our members use checklists and other techniques to ensure that they've received this information from their

suppliers.

Because some of the major food allergens are common in the food supply, milk, wheat, egg and soy, for instance, our members do not limit their information collection to the obvious or major ingredients.

Egg protein that may be a component but not a characterizing flavor of a sauce is a good illustration of this. The food processor that uses the sauce in the formulation of the food will obtain information from the supplier that egg protein is present, usually from the ingredient labeling on the sauce. And that information will be carried forward to the label of the finished food.

Regarding major food allergens that are components of additives that might qualify for the incidental additives declaration exemption, NFPA believes that FDA has already made its views very clear that such allergenic components are not exempt from declaration. NFPA advises its members in a way that's consistent with FDA's interpretation and policy.

Although scientists have been studying the issues of threshold levels of allergenic proteins

that trigger an allergic reaction, so far there are no established thresholds. This raises questions regarding the meaning of both insignificant quantities and absence of technical or functional effects in the finished food with respect to those food allergens, and both those conditions must be met in order to qualify for the incidental additives exemption.

In addition, the absence of solid scientific knowledge about the quantities of major food allergens needed to trigger allergic reactions argue strongly for FDA not to codify the specific exclusion of major food allergens from the incidental additives exemptions. The reason for this is plain. As food allergy science advances, it is likely to become increasingly evident that there are reaction thresholds. That is quantitative levels of food allergens below which allergic reactions do not occur.

Discussing the threshold concept is a meeting for another day with a group of experts different from this panel. Nevertheless, we urge FDA to be cautious and refrain from codifying an allergen exclusion of the incidental additives exemption at this time. If FDA were to codify this

exclusion, it would be a very difficult and long process to reverse the rule or selectively reverse the rule which is more likely to be the case. Thank you very much.

[Applause.]

DR. LEWIS: And Mr. Hallagan, please.

MR. HALLAGAN: I'd like to thank the agency and our allied associations for the opportunity to participate today. I'm representing three trade associations today: the American Spice Trade Association, the Flavor and Extract Manufacturers Association, and the International Association of Color Manufacturers.

Our members manufacture spices, flavors and colors that are included in a wide variety of foods and beverages.

One point I'd like to make to start is that our products, the bulk of our products, go into consumer products, foods and beverages, and are therefore not sold directly to consumers so our labeling requirements are different from consumer product labeling requirements.

But our main mission is to support our customers and to provide them with all the information they need to comply with all labeling

requirements or all labeling needs such as allergy labeling.

All of our member associations are members of the Food Allergy Issues Alliance and all support the guidelines.

Spices are listed by the FDA in the Code of Federal Regulations. There's a very long list of spices and has been mentioned, none of them are listed as allergens or considered allergens or the source of allergenic protein material.

The current FDA labeling rules do allow for the generic declaration of spice as providing for the inclusion of a variety of spices in a food product. Other materials that may be included in a mixture must be labeled and are subject to other labeling requirements, but an important point to keep in mind is that the spice industry is fully committed to providing information to its customers, in other words, food and beverage companies that incorporate spices into finished foods.

So if a material that originates from one of the eight materials that are considered allergens, if proteinaceous materials from those eight are used in a spice mixture, then the spice

manufacturer is committed to providing that information on its label so its customer can label as well.

In terms of flavors, the FDA has listed a variety of flavor materials in the CFR, and I've provided the citation. In addition, there is a longstanding industry GRAS panel known as the FEMA expert panel, which has done thorough safety evaluations on about 2,000 flavoring substances, and this list is available from FEMA and we're happy to provide it upon request.

This information has also been shared with FDA and these additives are included in the agency's database. None of the single chemically defined flavoring substances are considered allergens. These are individual substances that may be derived from natural sources or produced synthetically. None of them include proteinaceous material which would cause an allergic reaction.

The current FDA labeling rules, as I provided the citation for here, allow that flavor may be declared in a generic manner, but it's important to note that other materials included in a flavor would have to be labeled for with the exception, of course, of incidental additives and

processing aids, but the flavor industry, like the spice industry, is committed to providing information on allergenic materials that may be used in a spice mixture because flavors are complex mixtures.

They are a number of individual flavoring substances and other materials that are combined to provide the flavor that provides the taste to the variety of foods and beverages that we all consume.

FEMA has been very active in the allergy area beginning in 1997 when FEMA sponsored an education session for its members, the FEMA Allergy Workshop. The impetus for this workshop was the release of the 1995 FAO Technical Consultation on Food Allergens, and FEMA took the big eight list from that FAO consultation, made it available to its members, and in a self-regulation program established guidelines for the labeling of flavoring substances that are sold to consumer products companies. We had very good compliance with self-regulatory initiatives, as evidenced by the FEMA GRAS program. So we've had very good compliance so far with the allergy guidelines.

The FAO guidelines are very largely consistent with the Food Allergy Issuance Alliance

guidelines as well.

In terms of colors, the last group of substances I'd like to deal with this afternoon, large number of color additives are listed for use by FDA. They've been very thoroughly evaluated for safety. None of them are listed as allergens, but as Dr. Jacobson mentioned earlier, some scientific data indicate that carmine and cochineal may be able to cause allergic reactions.

We have encouraged our members, of course, to declare that whenever it's present in a mixture, and a number of consumer products companies also voluntarily declare it.

Certified colors must be labeled already specifically on the ingredient line. Exempt colors may be declared generically, but again any components that are derived from the big eight, we are encouraging our members to declare.

Thank you.

[Applause.]

DR. LEWIS: Just before we begin our panel discussion, let me remind you that if you do have questions, please do write them on the cards, pass them to the aisles. They will be collected.

Okay. For this particular panel, who

would like to open with a comment or a question? Dr. Falci.

DR. FALCI: This is Dr. Falci of the Food and Drug Administration. My question is generally I guess about flavors and colors and spices in the sense that I agree with you. A lot of them apparently don't appear to be allergenic per se, and I was trying to get a feeling for exactly how many times, for instance, you would put a flavor, for instance, as a single chemical entity into a food per se, or would it be mostly put into a food via a delivery system where the flavor would be on some set of substances and then potentially sprayed on a food product, for instance?

Isn't it mostly true that the delivery system for flavors, even colors and spices, would be sprayed on foods and that the delivery system would have potentially allergenic components in it, and that it wouldn't necessarily be that a matter of the flavor being there in a small amount, but the fact that the allergen is in the delivery system, per se?

MR. HALLAGAN: Well, flavors are used in a variety of ways. Dr. Falci has just described what we refer to as a spray dry flavor system. Dr.

Falci is correct. Flavors may be used in that way in addition to other ways. If a flavor is delivered on a system, in other words, incorporated into the food on a system which, for example, may contain a carbohydrate matrix or a carbohydrate substance to carry the flavor, then we have encouraged our members to declare that substance if, in fact, the delivery system contains a proteinaceous material from one of the eight listed groups of allergens.

So, yes, flavors are used in that way, and we have asked our members to declare those substances if they are contained in the delivery system.

DR. FALCI: And how often would this particular type of delivery system by used per se? I mean are flavors, colors and spices delivered 90 percent of the time in this matter in a food product?

MR. HALLAGAN: I don't know what the actual proportion is, but we could certainly get that information for you, but it is accurate to say that all three--flavors, colors and spices--can be used in that way. And, for example, flavors going into a beverage would not be delivered that way,

and that's a very large proportion of the flavor used; same with the candy. Spray dry flavors or colors or spices would be used on snack foods, for example, and again I'm not a technologist, but I can get that information for you.

DR. FALCI: Okay. Thank you.

DR. LEWIS: Other questions, comments? Michael?

DR. JACOBSON: Mr. Hallagan, you mentioned that your association favors voluntary labeling of substances like carmine that have been demonstrated to cause allergic reactions. Instead of relying on voluntary action from companies, would you support mandatory labeling of those through legislation or regulation?

MR. HALLAGAN: Well, our members' products are not the products that consumers actually consume in the majority of circumstances. It's our customers' labels that would be impacted. We're committed to providing that information to our customers and for flavors, colors and spices, as far as we're concerned, the initiative can be mandatory or voluntary.

Our members intend to provide that information to the customers, and that's our

commitment and that's what we've been doing for the last about four years.

DR. LEWIS: Other questions from the various panelists?

DR. FALCI: One more. Incidental additives--sort of it could be a learning curve here as far as incidental additives are concerned. There's been a lot of opinions or opinions expressed that incidental additives simply were not put on labels in the past, and although the agency has expressed the desire to have the food allergen in incidental additives put on the label, we started that policy and we suggested that policy back in 1996, it takes time to get through the industry.

But could you, maybe members of the panel here, suggest ways of making industry more aware that incidental additives are really to be put on the label when a food allergen is present? What are the types of things that you would do to try to improve that in the industry?

MS. HILDWINE: Well, I'll tell you the very first thing that I do is remind our members that the incidental additives exemption is not easy to come by. That regardless of whether your food

ingredient is identified as one of those suitable classes of ingredients that may qualify for the incidental additives exemption, that, in fact you have to pass two parts of--well, you have to pass both parts of a two-pronged test in order to qualify for the exemption.

Now, typically, these incidental additives are going to be ingredients carried over from a previous component of a food, but the regulation, I think, reads very clearly that that component in order to be exempt from declaration must be present in the food at an insignificant level and have no technical or functional effect in the food. One of them is not sufficient for declaration.

And I like to draw the example of, say, a flow agent in a seasoning blend. Say, the flow agent silicon dioxide has a functional effect in the seasoning blend. When that seasoning blend is added to a wet ingredient, the silicon dioxide loses all of its technical or functional effect. So when you add the seasoning, probably at a low level, to a food, and it's got the silicon dioxide, then, in fact, that substance may pass both prongs of the test, that it is present in the finished food in an insignificant amount and has no

technical or functional effect in the finished food.

Well, what applies to silicon dioxide in the seasoning blend may not, for example, apply to say a wheat extracted ingredient that's in the same seasoning blend, and that would not be exempt, so you really have to look at this component by component and make sure that every component that's carried forward passes both prongs of the test. So we do a lot to educate our members on just exactly what that exemption means.

DR. FALCI: How do you do that? Do you call them in? Do you have conferences? What?

MS. HILDWINE: Well, what I just told you that seemed to appear off the top of my head, you know, is not spontaneously there. It comes from years of advice to our members one on one, as we go--we do their label reviews. NFPA does this, reviews labels, as one of its benefits to members, and answering their questions. When they ask for clarification on the incidental additives exemption, I get a lot of questions regarding the incidental additives exemption and personally walk them through it every time.

DR. JACOBSON: Dr. Falci, the FDA

certainly could accelerate the learning process by identifying some products that have unlabeled incidental additives and find them misbranded, the allergenic incidental additives, and find them misbranded and remove them from the market. That would speed up the learning process considerably, I believe.

[Applause.]

DR. LEWIS: Other questions? Well, while you're thinking of more questions, we do have three from the participants here today. One is for Anne Munoz-Furlong. It's actually a two-parter, Anne.

Would milk allergic individuals know to avoid butter or cream or should these be identified in the ingredient panel as milk?

And the other is should only the top eight allergens be disclosed in favors and spices or more?

MS. MUNOZ-FURLONG: Okay. The question about whether the milk allergic individual, what their understanding of milk products and byproducts are is going to be depend on each individual. The people that are more aware of it, probably the parents, the people closer to the patient, are going to be very aware that yogurt or butter are

milk derived. People as we move away from the circle of care for that child may not necessarily make the connection and we see this over and over again when we're talking to grandparents and other caregivers of the child.

So our suggestion would be to always err on the side of safety and declare that it is milk after butter or any other of these terms to make it very, very simple to follow.

The second part of the question should we look at only the top eight or all of the allergens, I know there's a study that's been done that looked at the foods that had been implicated in reactions, and there were somewhere around 160 foods on that list. That's an enormous task.

What we would recommend again is to stay focused on the 90 percent of that problem. Once we figure out what the solutions are there, we can hopefully then quickly come by and address some of these other issues.

DR. LEWIS: The next question I have is stated as follows: If spices are not considered allergens, then how can one have an allergic reaction to allspice as referenced by Ms. Munoz-Furlong? If there have been reactions to

spices, then what motions are in place to address these issues?

MS. MUNOZ-FURLONG: I want to clarify my position. I am not aware of any reactions to a particular spice. The bulk of the work that we do is to look at those top eight allergens. If they appear in anything, such as a color, spice or flavoring, then we want those listed out on the label.

DR. JACOBSON: I was actually the one who mentioned allspice, cardamon and coriander. In the paper, Sue Hefle's paper, listing 160 or however many allergenic foods, those are included, and there are varying levels of evidence for those allergens, and I think there's going to be a gray area where there will be for some of the foods, there will be very limited, more anecdotal evidence. For other foods, there will be double-blind controlled studies, food challenges, that establish that it is allergenic, and then I think somebody will have to decide, well, how much evidence do you need?

How many cases of demonstrated allergenicity do you need before you require disclosure?

DR. LEWIS: The next question I have focused on the concept of thresholds. What would be the threshold that is the minimum level of an allergen that would have to be declared? If the level is zero, how would the manufacturers test for that?

MS. HILDWINE: I brought this up so I think I better field it. There is a lot of scientific work that's going on in this area. I'm not an expert on thresholds and certainly I really couldn't speak to quantities, but a lot of scientists are devoting a lot of attention to determining what are the levels that would trigger allergic reactions.

The author of this question has definitely pinpointed a problem, and that is that if we are talking absolute zero, then that's very, very difficult to achieve with respect to allergenic ingredients or for anything for that matter.

DR. JACOBSON: I agree that it's a tough problem. Fortunately, the assays don't get down to parts per billion, but they're measuring levels that presumably are allergenic. I think the presumption should be that the substance is listed, the wheat or soy or whatever, if it's known to be

there as an incidental additive.

But perhaps companies should have an opportunity to demonstrate that at such and such a level, something does not pose any risk of allergenicity. And right now I don't know that there's any evidence for a threshold, but there should be an opportunity to exclude labeling of incidentals if they do fall below some demonstrated threshold.

DR. LEWIS: I'll wrap my last two questions into one large question, although they're not entirely similar. The first is isn't it time that out of the three issues discussed today, this, meaning Panel III, holds the most risk for the food allergic consumer? Is the industry doing anything to prioritize this as the first issue?

And then a second part of this: Mandatory labeling is a zero sum equal expense for all manufacturers. What incentives are there for manufacturers to deal with the cost of voluntary labeling?

MS. HILDWINE: Well, I'm not absolutely certain that this is where the bulk of the problem of undeclared allergens is. I think we spent a lot of time in our second panel this morning talking

about good manufacturing practices, and let's say significant levels of food allergens that are undeclared in food products. So I think you've got some good sense of what that's like from the report of the FDA inspections.

So I think that certainly manufacturing practices are really where we may need to spend a lot of attention, you know, in resolving labeling things.

The issue of undeclared allergens that may be present in flavors, colors, spices and incidental additives certainly is also a very important issue because it involves undeclared allergens and that's an important public health concern. But whether that is top of the list I think is still open to some discussion.

As to incentives for the food industry to pursue voluntary labeling, nothing is quite as effective in the food industry as what we call peer pressure or the competitive marketplace, and certainly we know from the experience of food allergic consumers that they very much appreciate when food companies go to the trouble of putting food allergen information on their labels on a voluntary basis.

More and more companies are doing this, and they're beginning to be much more responsible about the way they do this, and consequently, you know, particularly if you're in a sector of the industry where you compete with some major companies that are already doing food allergen labeling of an advisory nature, this is something that you're considering because food allergic consumers more often than not are calling you up and asking you why isn't it there?

And in addition to the pressures of the marketplace, the pressures of consumers certainly have something of an impact on what the food industry does.

DR. LEWIS: Any last comments or questions from anyone else on the panel? If not, what we'll do now is turn to the last component of our program, the public comment.

Just a couple of announcements and reminders before we do that. The first is that for these issues, the FDA docket is still open. People who are interested in submitting written comments on these particular topics are more than welcome to do so. The docket is still open.

Secondarily, I need to be very clear about

what are the issues that are being addressed today. It is food labeling. It is not latex gloves. It is not celiac sprue, and it is not restaurant labeling. Those are not topics of today's discussion.

What we'll do at this point is take a 60 second stretch break while this podium is lowered down so that our speakers will be able to make their comments from the floor. So bear with us for 60 seconds while we arrange up here and then we'll be right back with our first speaker.

[Whereupon, a short recess was taken.]

DR. LEWIS: All right. The procedure is that we will go down the list of persons who have registered to speak. We ask that you very briefly introduce yourself. You are being timed for three minutes. I do apologize if I mispronounce your name. I'll try the best that I can. You can correct me once you do get up there, but again it's three minutes and we would appreciate your moving along appropriately.

The first on my list is Victoria Geduld.

MS. GEDULD: My name is Victoria Geduld. I'm a concerned citizen and mother and I am with my daughter Nancy Geduld, who is six years old and a

student. Due to time constraints, I will not go into a lengthy of history. Suffice it to say that Nancy loves playing with her friends and sisters and going to the park.

It's a sunny day in August and rather than doing all these things on this Monday, she chose to sit with me because the most important thing in her life is safe food. Misleading and unclear labels can kill her and she knows this firsthand.

My daughter Nancy has an acute anaphylactic reaction to peanut proteins which is a fancy way to state the simple fact that trace amounts of a simple and common food can kill her.

A few years ago, Nancy ate a chocolate Kellogg's Rice Krispie treat that said nothing of peanuts or peanut traces on the label. After a few bites, she said, Mommy, this has peanuts. I read the label. Nothing. She began to swell. I gave her medicine and we were fine. Within a few months, these same treats began to carry the label "may contain peanuts."

The traces must have been small. Were the traces larger, we know from history, Nancy would have had an injection and she would have been hospitalized, if she had survived. At four years

old, Nancy learned not to trust labels.

Foods must be labeled in plain English so that Nancy at six and myself, her father, grandparents, relatives, teachers or caregivers can read the label and know what's inside. If I have as a consumer have a question regarding the food, I should have a number on the label to call.

In a recent example, the outside container of the same Kellogg's chocolate rice krispie treats said that they did not contain nuts, the individually wrapped treats inside said "may contain peanuts." As it turned out, the line had been changed and made peanut free, and the labels on the outside had been changed to reflect this.

The individual wrappers inside had not. A confused consumer should be able to contact a food manufacturer. Small packagers can get waivers from the government, but luckily there are few who would qualify. Most packages are large and should be required to provide access to the company in the case of an accidental ingestion or an emergency or a question.

In addition, any information about the ingredients in the food should be listed in the ingredients section of the label. "May contain"

warnings do not help at the bottom of a package if the ingredients are printed on the top. We had a near accident in such a case. The warning was next to the company's address, catty-corner to the ingredient section.

If it has to do with the ingredients, put it in the ingredients listing. With the purchase of food for an allergic individual, there is a ripple effect. For the millions of allergic people, there are tens of millions who are affected. Think of the number of people who are involved in feeding a single child.

All these people will be served with government legislation demanding accurate and readable labels. In addition, all these people will be unnecessarily inconvenienced by a "may contain" label spread on packages. No matter what manufacturers must not be allowed to put a warning label on foods because it is easier or more convenient than actually monitoring the food supply. The government must ensure that labels are accurate, not just slapped on.

In order for my daughter to trust her food supply and get back to the business of being a child, any allergens must be included in the

ingredients section. There can be no exemptions. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next please Pamela Hughes. If Pamela Hughes is not here, we will move to Joseph LaRochelle.

MR. LaROCHELLE: My name is Joe LaRochelle and I would like to tell you what it is like to have a life threatening food allergy and why it is so important to have accurate and dependable food labels. I'm a 21 year old who lives in Dairy, New Hampshire and a senior at St. Anthem College in Manchester, New Hampshire.

Besides having asthma, I'm also deathly allergic to peanuts and tree nuts. If I eat even a trace of these, I don't just get a stomachache. In my short life time I have had more than ten severe allergic reactions. When I was 13, I almost died. I had a chocolate chip cookie that contained walnuts. My symptoms started with a simple stomachache, but after less than one hour, I started having hives, itchy mouth and throat, breathing problems. All the while my throat started to close and I began to lose consciousness.

Doctors said that if I wasn't not a mile

from the hospital, that I probably wouldn't be standing here right now. After two to three injections of epinephrine, two shots of benedryl, two nebulizer treatments and a oxygen mask, I was released from the hospital five hours later when my condition stabilized.

Every minute of my life I must be on guard by reading all ingredient levels with how to read a label card handy and my epinephrine in the case of a severe allergic reaction.

It is critical that food labels be accurate, clear and dependable to help me avoid potential life threatening allergic reactions because peanuts and tree nuts often show up unexpectedly in the most unlikely of places.

Besides reading all ingredient labels, I am constantly watching for product recalls because of undeclared peanut or tree nuts. Because of that, I give high priority to the Food Allergy and Anaphylaxis Network's special food allergy alerts that notify me in the event these things happen.

In the last few months in my state, an ice cream manufacturer recalled product with undeclared pistachios, a cereal maker had undeclared almonds, potato chips with undeclared peanuts, brownies with

undeclared almonds, yogurt raisins with undeclared peanuts, and I could go on.

This simply underscores the fact they all don't get it right all the time. I would just like to briefly comment on the "may contain" statements. I never eat foods that say may contain peanuts or tree nuts, processed in the same facility as peanuts or tree nuts, or processed on shared equipment.

I'm grateful that some manufacturers have alerted me to the potential presence of an allergen, but would prefer they take the necessary steps to prevent cross-contamination in the first place.

In recent years, I have seen many more products with these statements on the label, a trend that is limiting my choice for foods that I can safely eat. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next, please, Julie Reinhard.

MS. REINHARD: My name is Julie Mendel Reinhard. I am the mother of a three-year old peanut allergic son. I am here not only on behalf of my family, but on behalf of 2,945 consumers

representing 27 states who have signed a national grassroots petition seeking regulations to make food labels more accurate.

Since I learned about my son's allergy the hard way, in the emergency room as doctors battled to save his life, I have been challenged with keeping him in a peanut free environment. This means that I must read the label of every product that comes into our home and indeed every label of food my child may eat or come into contact with outside the home.

But that's just the beginning. After reading the food label, I must call the manufacturer to determine if the food has been made on shared equipment and therefore has the possibility of cross-contamination.

This is because manufacturers do not reliably state whether peanuts are or are not in the product. Furthermore, even after I call the manufacturer, I often do not get accurate information. Sometimes I leave a message on an answering machine that can go unanswered for a period of weeks, and sometimes forever.

Other times I talk to a consumer rep who reads from a written policy statement, but won't

send it, and is unable to answer basic questions. Often I have to make at least three calls before I even talk to an informed person. The first call is typically to get the phone number of the company.

Worse, it is the rare occasion when I am told that the risk of cross-contamination is de minimis. Therefore, I am unable to rely on the label itself to know if the food is safe for my son, and yet strict avoidance is the only sure way to keep him safe.

In addition to the FDA's inspection, research at the University of Nebraska documented that peanut residues were detected in 21 out of 111 products with either precautionary labeling on peanut listed as a last ingredient and in 33 percent of foods with no labeling in any form.

The researchers concluded that quote, "Despite vigilant monitoring of food ingredient statements by peanut allergic individuals, significant levels of unlabeled peanut residues can be encountered in food products."

Finally, a study published in 1997 found that while the threshold dose of peanut protein varies, as little as 100 micrograms provoked symptoms in some peanut sensitive individuals. For

each of these reasons, I strongly urge the FDA to prescribe regulations requiring manufacturers to use plain English and commonly understood terms in the ingredient statement like egg, milk and peanut, rather than a scientific term, and to adopt the proposed ingredient facts label put forth by CSPI.

Further, I implore the FDA to mandate that allergens contained in natural flavors and spices be listed in a parenthetical after the general term is used, and to clarify the incidental additive regulations by stating that those containing allergens are significant and therefore not exempt from label declaration including substances migrating to food from equipment.

Third, I ask you to adopt the allergen control procedures recommended in the attorneys general citizen petition.

Finally, it is with profound gratitude to the cochairs of this national grassroots campaign that I submit the following petition to the FDA for its careful consideration. Here it is:

(1) Put allergen regulations as an "A" priority on their 2002 agenda;

(2) Prescribe allergen control procedures for companies to follow in cleaning equipment to

reduce or eliminate the unintentional presence of a known food allergen in the finished product;

(3) Mandate precautionary labels on foods if allergen control procedures and GMPs do not eliminate the unintentional presence of a known food allergen and the presence of such allergen poses a risk to human health;

(4) Inspect manufacturing plants to determine if they are complying with the laws and regulations; and

(5) Punish companies who are not in compliance with the laws and regulations.

As the governmental body responsible to protect the health and safety of our Americans, these relatively simple measures can profoundly impact the safety of millions of Americans who suffer from food allergies. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next we have Elizabeth Carus and in order not to surprise you folks, after Elizabeth Carus, we would be addressing Gayle Rubin. Is Elizabeth Carus here?

MS. CARUS: My name is Elizabeth Carus, and in addition to being severely allergic to wheat, I also have celiac disease. Prior to being

diagnosed with celiac disease, I was trying to follow a wheat-free diet. I know how to read the labels. I know what to look for, and until I went and had to follow a gluten-free diet, I was obviously missing a lot of hidden wheat.

Upon going on a gluten-free diet, I ceased having asthma problems, which included going to the emergency room quite a few times, and obviously there was enough in the food that's hidden even after calling companies to have given me problems.

When I call companies to verify whether things are wheat free and gluten free, the biggest problem I have beyond being told yes, it is, having the allergen so I can't eat it at all, is to find out that the company will tell me that they don't know if there's cross-contamination, not because in their company they have a problem, but they don't know from their suppliers. And when the company tries to find out from their suppliers, because they do want to know whether it's gluten free since that's where I'm at, it can take them months.

They can write many letters and in the end they can say we don't know because we can't find out from our suppliers. And that to me is a big problem. And that's probably about half the

companies I call is what I find out. And these are companies that want to be able to tell me that things are okay, that are being careful about telling me what's in their food, and they don't feel comfortable telling me because they don't know if there might have been a cross-contamination.

And basically that's what I wanted to pass on to you about that with the food products and things.

[Applause.]

DR. LEWIS: Thank you. Next is Gayle Rubin and following Ms. Rubin, if she's here, Judith Schreiber.

MS. RUBIN: I brought some props. Hi. My name is Gayle Rubin, and I'm here supporting the celiac support groups. It says something different on your listing. I'm not sure what that was.

Anyway, what I wanted to tell you is that gluten intolerance of celiac disease is a genetic disease that affects between one in 150 or between one in 250 Americans. And that is basically new information, and if you take that and you add that to--figure out from what our total population is, you're looking at 1.5 million people roughly.

If you take the related disorders, such as

Addison's Disease, other allergies, asthma, arthritis, attention deficit disorder, autism, cancer, diabetes, epilepsy, irritable bowel syndrome, lactose intolerance, mental disorders, multiple sclerosis, osteoporosis, psoriasis, scleria, sleep disorders, which affect another six or seven million people, you're talking about a lot of people who need label clarification.

That's basically the reason I want you to understand it's not--somebody made mention of--it's not about celiac disease. It's not about celiac disease. It's about people who have to know what's in the foods they eat. It's a lot of people.

And as you do know, or you probably already know, celiac disease requires a strict adherence to 100 percent gluten-free diet for life. That includes trace amounts, and we can't have it. So I did want to show you a picture of what celiac--I've taken this out of a medical book. It's actually Fishbind's, and I wanted to show you a picture of what it looks like, when you don't adhere to 100 percent gluten free diet.

That comes about because the villi, which is the way you normally ingest food are stunted, they're cut off, and then what happens is, you

know, you can't get food. You start malabsorbing. You can't get nutrition to yourselves so I mean it's not minor.

The other part, I guess, of that is that there's many, many places of hidden sources of gluten that are found in ingredients of processed foods, and I can show you, you know, these Lays potato chips are totally gluten free. These Lays potato chips are not gluten free. And without calling the manufacturer, you don't know that.

Another type of example I brought you is this is a package from Europe, and this is what it looks like when they say it's gluten free. They actually have this little wheat symbol with like a no smoking slash through it, and they have that sign one, two, three places on the package, plus in five languages it's written gluten free, and it's written one location, two locations, on the top. I mean so there are six locations on a label that our American manufacturers say there isn't enough room on the package to put anything. So I will cut off at that point. Thank you.

[Applause.]

DR. LEWIS: Thank you. Judith Schreiber and then I believe Peter Skinner following.

MS. SCHREIBER: Hello. My name is Judy Schreiber. I'm a senior public health scientist in the New York State Office of the Attorney General Elliott Spitzer. And I am here today to offer our comments on the important public health issues of labeling food products containing allergens.

As one of nine states' attorneys general, our office submitted a petition to the FDA to amend its regulations on food labeling and manufacturing practices to better protect consumers from exposure to potentially life threatening food allergens. We are grateful that the FDA is taking consumers' concerns seriously and has made strides to address these important public health issues.

In the May 2000 petition, the attorneys general asked that the FDA: (1) require food manufacturers to label products with actual or possible presence of allergenic substances in foods; (2) require food manufacturers to provide a toll free number to enable consumers to contact knowledgeable customer service representatives about the ingredients contained in the foods; (3) to require manufacturers, food manufacturers, to declare natural and incidental additives derived from the big eight allergens; and, finally, to

require food manufacturers to adopt good manufacturing practices aimed at preventing cross-contact with allergenic substances.

Regarding some of the questions that you posed for this hearing, we do believe that mandatory language is the only way to assure that the label contains the necessary information upon which the consumer can make an educated choice about the safety of the food for their family's circumstances.

Two, we do recommend that the labeling and good manufacturing processes be exercised--the FDA should exercise its authority and adopt the recommendations in the attorneys' general petition. The New York State Attorney General is considering future steps if the FDA neglects this important public health role.

Finally, we agree with the FDA that the declaration of allergenic ingredients and incidental additives in flavoring, spices and colors is necessary for consumer protection. The petition of the attorneys' generals recommends amending certain parts of the regulation, and we will be submitting written comments elaborating on where we feel these changes could be made.

We strongly urge the FDA to codify its policy, to specifically state that incidental additives that are food allergens are not exempt from labeling and must be declared in the ingredient statement on the label.

We also urge the FDA to require mandatory labeling to appear prominently and conspicuously on the information panel so that consumers can readily identify where that information is located.

A speaker earlier today said that the FDA product recall program for allergenic contamination demonstrates that the system is working. I would say that that same example shows, in fact, that the system is broken and that it must be fixed. Having to recall products or having to have children and adults go to emergency rooms for care is not a preventative public health measure, and I urge that the system being broken, let's fix it. Let's give consumers the life line they need by having adequate labeling on food products. Thank you.

[Applause.]

DR. LEWIS: Thank you. Is Peter Skinner with us today?

MS. SCHREIBER: No. He was unable to make it. His wife went into the hospital.

DR. LEWIS: Thank you. And our next scheduled speaker is Catherine Tretheway. Following Catherine Tretheway will be Javier Trujillo Arriaga.

MS. TRETHEWAY: Hello. My name is Catherine Tretheway. I am an attorney and I assisted the New York State Attorney General in the preparation of the petition which has been the subject of today's discussion. More importantly, I am the mother of a five year old daughter who has a life threatening allergy to peanuts.

I am also an active member of a support group for families who are dealing with peanut and nut allergies. I asked to speak today because I think it is important that the FDA know the source of this petition. This is truly a document prepared by consumers for consumers. In drafting the petition, I not only drew from my own experiences as the parent of a food allergic child, but also from the experiences of the many parents with whom I have talked or corresponded with during the recent years that I have started my work on food allergy issues. Many of those parents are in the audience today.

The petition is not a wish list for food

allergic consumers. Rather it represents what consumers truly need to protect themselves and their loved ones from unintended consumption of food allergens.

We need better manufacturing practices to avoid cross-contamination. We need accurate labels. We need clear and easy to read labels. We need phone numbers on the labels so we can contact manufacturers with our questions. Above all, we need consistency in labeling and manufacturing practices so that my mother-in-law, my child's babysitter, and others, and especially my own daughter, can look to one spot on a food label and readily and quickly ascertain whether a food is safe.

As the parent of a food allergic child, I appreciate the efforts of the Food allergy Issues Alliance in issuing guidelines for better good manufacturing practices and labeling. However, even after all our discussion today, I can only conclude that consistency in labeling can only be achieved through regulatory reform. I urge the FDA to adopt the proposals set forth in the attorneys' general petition. Thank you very much for your time.

[Applause.]

DR. LEWIS: Thank you. Next Javier Trujillo Arriaga, if that person is present. If not, Claudette McIntyre. Neither Claudette McIntyre or Javier Trujillo Arriaga. Then the next is Ron Barenburg.

MR. BARENBURG: Thank you. My name is Ron Barenburg. I'm from a company named Lynx Street. We're involved in bar code symbology. There's a new bar code called reduced space symbology and composite symbology that allows more information to be put into less space.

Now, next one, please. I'm sorry. That's the wrong one. I'll go from here. Just forget it. How reduced symbology and composite symbology, which are globally recognized as bar code standards, can alert consumers to allergies in food products. Today manufacturers use what's called a UPCA code. That's the bar code sticker that's on every product. The upgraded version of it approved by the Uniform Code Council is also a UPCA bar code, but what's different about it, it is a portable database in that it can contain a lot more information.

Right now it's available today. It can be

implemented by manufacturers phasing into RSS-UPCA bar codes. Retailers can upgrade or change their scanners on their normal scanner cycle. Today's UPCA bar code contains only the manufacture number and the product ID number. With the allergen warning using RSSCS-UPCA bar code, the following can contain this information. This is what today's bar code looks like. That's what's on every product that comes to market.

With using and phasing into as an adjunct to the warning level in human readables, scanned with the same UPCA code, it can say warning: contains eggs. If you wanted to put a warning: contains eggs and best used by date, it would be a similar label. It would just be a little larger. All these can be put into the same space that a normal UPCA code can use today.

The benefits to the retailer. Besides the obvious concern for their customer's health, it would provide evidence that the consumer was given documented warnings with receipt of their purchase. Retailers will eventually upgrade anyway to support produce at variable weights and measures converting to RSS-CS.

The benefits to the consumer are obvious.

Besides having the "may contain" warning in human readables, the scan bar code would print it out on the receipt alerting the consumer to the allergen warning, and if the consumer has a question, a checkout clerk would scan the product and verbally advise about any allergen danger before purchase.

In conclusion, RSS bar codes can provide more information in less space, not only for allergen warnings, but for best used by dates, contraindications for other foods or drugs, and by providing batch and lot numbers, trace contaminated foods more quickly.

I was drawn to this when I went to do some research on this and realized when I picked up with my 57 year old eyes a label and tried to read it, and I didn't have my reading glasses, how nice it would be just to be able to scan it at the register and see it in big letters, and I think it would help consumers tremendously. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next, Joanie Janicki. And following Joanie Janicki would be Cliff Blaker.

MR. JANICKI: That's a bit of a discrepancy here. J. Janicki.

DR. LEWIS: J. Janicki. Our apologies.

MR. JANICKI: Regulation 21 CFR 1001.4(a) deals with food designation of ingredients, and the problem here is that the criteria are fairly vague. The regulations above, the FDA states that natural flavors and/or artificial flavors may be listed in a vague manner. As an example of this would be the problem that most commercial products contain certain ingredients such as modified food starch and/or natural flavorings. It is not possible to tell by this type of labeling what ingredients the product actually contains such as corn, potato or wheat which are common allergens.

This type of labeling can have serious ramifications to individuals with food allergies and celiac disease. I along with many other individuals who have food allergies urge the FDA to require manufacturers to list all the ingredients including trace amounts.

As a first step, my recommendation would be to simply add a line after the words "modified food starch natural." Instead of modified food starch or garlic oil rather than spices. In Europe, they specify yes or no gluten and have a sign in front of the package similar to that of a

has one place to go to look for the information on the product label.

Now, there is one area where I think my experience as a businessman makes me an expert and that's the talk about voluntary compliance rather than mandatory compliance.

Now, I think the voluntary efforts that have been spoken about today should be applauded, but they cannot really eliminate potential problems. Some companies will be more proactive than others, but there will always be companies that will drag their feet and not comply.

It's the nature of industry to resist regulation and to minimize costs. What we have here is a balance between cost and public health and it's the FDA's mandate to decide in favor of public health.

When statements were made about advisory labeling with the "may contain" wording, I think that what was identified as unavoidable cross-contamination in many cases really means contamination that's too difficult to avoid or too expensive to eliminate. Again, I think it's the FDA that has the responsibility to protect the public and not leave these critical decisions up to

individual companies to make, and I urge the FDA to keep that in mind.

Thank you.

[Applause.]

DR. LEWIS: Thank you. Next Jorge Hernandez Baez, followed by Gustavo Trevino. Mr. Baez, Mr. Trevino? Martin Shunemann. Anne Bailey. Mary Thorpe. Mary Thorpe will be followed by Anne Clarke.

MS. THORPE: My name is Mary Thorpe. I'm currently working at the Center for Celiac Research at the University of Maryland Baltimore, and I'm also representing myself as a person who is attempting to follow a gluten-free diet and thus a wheat free diet.

And as such, I can speak for other celiacs around the country. I would just like to focus on some of my frustrations in following food labels that haven't been touched on very well. Gayle Rubin mentioned secondary sources, and reading labels myself I notice that some cans of tomato paste list wheat flour as an ingredient. Don't ask me why it has to be there, but it is.

And then when I look at a jar of spaghetti sauce of barbecue sauce, it has tomato paste as an

ingredient, I'm left to wonder does that tomato paste have wheat flour in it or not. Sometimes you might see a parentheses that tells the ingredients in that secondary ingredient, but usually you do not. And that's something I haven't heard touched on very much.

So this indicates that some manufacturers are voluntarily doing this, but others are not. The same thing goes for soy sauce. Again, soy sauce has wheat in it most of the time. When soy sauce is a secondary ingredient, you don't know. So we have to avoid these things unless the labeling were there.

And I think that's what we'd like to ask for today is that the labeling be there so that we know and can make the choices for these sources of things. There are many products. Somebody just mentioned modified food starch. This is a question mark. You don't know the source of the food starch.

Some manufacturers are voluntarily saying modified corn starch so we can make an informed choice, but we'd like to see everybody doing that. Or say modified wheat starch if that's what it is. But just let us know.

There are other products like citric acid, MSG, stabilizers, monodiglycerides, dextrines, that can be made from different sources--corn, sugar or wheat--and we would like to know the source for those properties. All you have to do is put it in parentheses--(from wheat)--for each one. It wouldn't take up much space.

Alcohol and vinegar are controversial, but they may have wheat origins. There should not be protein products in those substances, but there might be. Some people are explicitly sensitive. We don't know the threshold of tolerance and so not knowing, we'd rather err on the side of safety. And just let us know what the source is so we can make our informed choice.

So whether it comes down to voluntary compliance by manufacturers or FDA codification, I would agree with many who would say that the manufacturers are trying, but we're still not there yet. It's been excruciatingly slow, and we'd like to see whatever is needed to speed up the process. We would hope the regulations wouldn't slow it down, but we just want it to be done. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next is Anne

Clark, to be followed by Esah Yip.

MS. CLARK: Good afternoon. My name is Anne Clark. The FDA has made the presence of allergens in food high priority. This is a good thing. Labeling food that contains peanut or tree nut allergens is a very good thing.

Labeling food that has or may have been handled with natural rubber latex gloves is not an acceptable solution or labeling as contains or may contain the incidental food additive allergen NRL. Currently natural rubber latex, or NRL, is approved by the FDA as an indirect food additive in light of the over 500 NRL lawsuits working their way through the American justice system concerning wrongful death, product liability, workmen compensation, and American with Disabilities accommodation. Manufacturers of NRL gloves have already begun the labeling process.

Standard wording reads something like this one:

In the unlikely event of an allergic reaction to these latex gloves, discontinue use and consult your health care provider. Caution: this product contains natural rubber latex which may cause allergic reaction. Great for food handling.

It says that on there. This product meets the U.S. Department of Agriculture specifications for food handling.

Now, I have seen and submitted to the USDA advertisements for NRL gloves which claim to be USDA approved and USDA accepted. I've been told by the USDA that they do not approve products. There is no such thing.

These gloves which I purchased contain a warning, a label, that really disturbed me. Some individuals may experience an allergic reaction to natural rubber latex products. Discontinue use if any reddening, burning or irritation is experienced. This manufacturing company will not be liable to individuals who experience allergic reactions to natural rubber latex.

Now, this manufacturer understands that their product can harm. Those of us who have experienced or witnessed someone having an allergic reaction to food handled by latex gloves understand these gloves can harm. There are safe, affordable alternatives. The allergens that are transferred on to food do not add to the nutritional value, preservation or flavor enhancement of the food.

This is important. We know of no way with

current scientific knowledge to determine a protein threshold level that would be safe for all users and would not trigger any allergic reaction to NRL.

Furthermore, the current FDA food code alerts the food service industry of the potential for serious adverse reactions from latex to latex sensitive individuals. Gloves made of NRL must be declared an unsuitable utensil for food handling. NRL approval must be amended so that gloves made of NRL are not an approved indirect food additive. Labeling in this instance is not the solution. Thank you.

DR. LEWIS: Esah Yip or Anita Klein? Next, Carol Roberts. Carol Roberts is here.

MS. ROBERTS: My name is Carol Roberts. I'm a 62 year old grandmother who has had many allergies to deal with most of my life underlined by celiac, but I'm not going to speak to that today at all. I'll send some information in. I would like to make a very simple suggestion and as I read through all three areas, and as I know that I've experienced just about every single one of the things that have come up in one way or another, I used to teach school, elementary school, and I used to be an elementary school principal, and I've

worked in the corporate world and done diversity training and done many things.

But what I thought about is we have a lot of people in this country who don't speak English. We have a lot of people in this country who don't know how to read. We have a lot of people in this country who don't have any knowledge whatsoever about what hydrolyzed protein or caseinate or any of these things are.

And I proposed a question to one of the panelists before who is not here about the integrity of whether or not if a person is allergic, say, to eggs, will they be allergic or sensitive to any byproduct from eggs? The answer was yes. And so, therefore, why do we need any other words except "eggs" on a label in terms of food being contained?

What I did was take a little bit of time and I used pictorial chart. And this is just an idea and a suggestion of taking the different food allergens of the eight allergies and I took and did a diagram of each one of them that's understandable by children. In the next column, I put the contains fish or seafood, listing the types, contains wheat or byproducts in words, and listing

all of the different names.

The symbols can have checks through them, next to them, into them, whatever would make the most sense and be least confusing to those who looked at a label. So each one of these things in terms of the terminologies that have been developed by each of the groups that are working on this could be incorporated into a glossary, put into a simple pamphlet.

These charts could be done in such a way that you have them in a very organized simple way. They could be laminated, put into posters, put into grocery stores, hospitals, nursing homes, anywhere where anyone is affected by these kinds of things in terms of it.

In terms of signaling where they go, using caution, yellow label--everyone knows yellow is caution--put it there right on the label right there and put the words in there with a little picture that says what it is, or use a stop sign, which is also a universal safety sign which children understand, so that if anyone just picks up that product, they know that they need to go and look at information on that label.

And so I would just suggest a very simple

adage like this to be able to simplify it down. You've got eight allergens. Use those eight words. We really don't need all the rest of them. Manufacturers could help by leaving a lot of products out of--a lot of these additives and so on out of their products in the first place and let's get back to basics and good nutritional food.

[Applause.]

DR. LEWIS: Thank you. Next, Rebecca Dugal, and following Rebecca Dugal, Anne Whelan. Rebecca Dugal. I take it this is Rebecca Dugal.

MS. DUGAL: This is Rebecca Dugal. I just wanted to say a few words while she's getting set up. We have some slides.

DR. LEWIS: Please continue.

MS. DUGAL: I wanted to thank the FDA for hosting this panel. I think it's wonderful that we're kind of moving along with food labeling and to all of the panel participants. I also wanted to thank my daughter for urging us to come and for not letting up on me in terms of making sure we could make the trip down here from New Jersey and help her with her presentation. This is something that's very important to her since she was about four in terms of being able to read the labels and